CONFIDENTIAL

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K003348

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
[21 C.F.R. § 807.92]

December 29, 2000

Submitter: ENSI-MED INTERNATIONAL Pty. Ltd.
5-7 Halleur Road
Harkaway Victoria
Australia

Contact Person: Jacqueline James or David Curie
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510(k) Number:	K003348
Proprietary Name:	E.N.S.I. Retractable Safety Syringe
Common Name:	Retracting Needle Syringe
Classification Name:	Piston Syringe (21 C.F.R. § 880.5960)
Manufacturer:	Uni-Ject Australia PTY LTD 19-21 Peninsula Boulevard Seaford, Victoria 3198 Australia
Predicate Device Information:	A claim of substantial equivalence is made to: Tri-Ject's ENSI™ Retractable Syringe (K000572)
Device Description:	The E.N.S.I. Retractable Safety Syringe is a retracting needle syringe. The syringe design employs a patented retractable mechanism that becomes engaged upon injection of the syringe's contents. Withdrawal of the plunger locks the needles securely inside the syringe barrel and meets the strength requirements of a sharps container.
Intended Use:	The E.N.S.I. Retractable Safety Syringe is a sterile, single use, disposable syringe for injecting fluids into the body, while helping to reduce the risk of sharps injuries.

In compliance with the requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification.

Safety and Effectiveness

The E.N.S.I. Retractable Safety Syringe is identical to the ENSI™ Syringe cleared by the Food and Drug Administration on February 24, 2000 (K000572). Both syringes consist of five separate components: the syringe barrel, the plunger, the patented retractable mechanism (with male luer fitting), a gasket, and lubricant. Both can be used to measure accurately 1, 2, 3, 4, and 5 mL of fluid. Both have a transparent syringe barrel that is 2-3/4" in length and has a 1/2" inner diameter. Both have a scale that consists of approximately 5/16" wide markings for each mL of fill volume up to 5 mL maximum. The total mL volume mark is further identified with the appropriate fill volume, i.e., 1, 2, 3, 4, and 5. Between the full mL volume marks there are 0.2 mL volume marks which are approximately 3/16" wide on both syringes. Additionally, there are 0.1 mL volume marks provided for the first 2 mL of fill volume that are approximately 3/32" wide.

With respect to substantial equivalence, the Federal Food, Drug, and Cosmetic Act states:

> (A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device--
>
> (i) has the same technological characteristics as the predicate device . . .

21 U.S.C.A. § 360(c)(i)(2000).

Because the E.N.S.I. Retractable Safety Syringe is identical to the ENSI™ syringe cleared by the FDA on February 24, 2000, the devices are substantially equivalent.

According to the *Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features* (ODE, March 1995), "[s]imulated and clinical use tests are not required for devices that are identical to a legally marketed device or have minor variations." (Supplementary Guidance at 21).

In the 510(k) filed by Tri-Ject International Corporation (K000572), Tri-Ject discusses a simulated use study conducted at two hospitals and a large medical center in which more than 100 investigators tested 580 ENSI™ syringes to evaluate the effectiveness of the product at injecting fluids into a patient. According to Tri-Ject's summary of safety and effectiveness, all of the injections were successfully completed and 100% of the investigators had a positive response to the syringe evaluation. Tri-Ject also reports that bench testing of the ENSI™ syringe confirms its compliance with the applicable performance standards established by the International Standards Organization.

Tri-Ject also discusses a simulated use study by doctors, nurses, and emergency medical technicians. In that study, over 580 ENSI™ syringes were tested to evaluate the safety of the product. No injuries were reported. Tri-Ject also stated that bench testing of the product confirmed its comparability with with the predicate devices for a variety of safety factors, including graduation accuracy. The biocompatibility testing demonstrated that the product is safe for its intended use. A risk analysis showed the risk of harm associated with the device to be relatively low. Tri-Ject reports that sterilization validation was conducted by a third-party laboratory, with acceptable results, and that pyrogenicity was evaluated, and those results were acceptable as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

ENSI-MED International PTY. LTD.
C/O Mr. Nap Curie
Managing Director
UNI-JECT Austrailia PTY. LTD.
19-21 Peninsula Boulevard
Seaford, Victoria
AUSTRALIA

Re: K003348
Trade Name: E.N.S.I Retractable Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: October 19, 2000
Received: October 26, 2000

Dear Mr. Curie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K003348

Device Name: E.N.S.I. Retractable Safety Syringe

Indications for Use: The E.N.S.I. Retractable Safety Syringe is a sterile, single use, disposable syringe for injecting fluids into the body, while helping to reduce the risk of sharps injuries.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003348